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510(k) Summary

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Summary Preparation: April 30, 1996

Device: MicroSpan Hysteroscope

Predicate Devices: Imagyn Hysteroscope
Imagyn MicroLap Laparoscope
Karl Storz Miniscope Straight Forward Telescope
Optimed Technologies Rigid Fiber Optic Hysteroscope

Device Description: The MicroSpan Hysteroscope is a small diameter, rigid, fiberoptic hysteroscope without through lumens. The device consists of an outer stainless steel shaft, inner illumination fibers, and an imaging fiber bundle. At one end of the imaging bundle is the distal lens and at the other is the rotatable eyepiece. An endoscopic light source is connected to the light post of the hysteroscope through compatible light cables. If desired, the eyepiece can be connected through a focusing optical coupler to a camera head which carries the image by cable to the camera.

Intended Use of Device: The MicroSpan Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Technological Comparisons: Light from a high intensity light source (e.g. xenon) is transmitted through illumination fibers to the distal end of the hysteroscope in order to illuminate the target object. The distal lens system focuses the image of the object onto image fibers, which then transmits the image to the proximal lens system. The proximal lens system magnifies and focuses the image onto an eyepiece at the proximal end of the hysteroscope for viewing and/or directly to standard video cameras, monitors and recording equipment. The MicroSpan Hysteroscope and the predicate devices all have equivalent technological characteristics.

Performance Summary Non-clinical tests were performed to demonstrate that the device performed according to its description. Testing included evaluation of optical and mechanical characteristics of the device and the effect of simulated reuses on these characteristics. The device was also evaluated for its thermal characteristics and biocompatibility.

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